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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/701,289	05/29/01	LAMBERT	P PM-275343/C1

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EXAMINER	
FORD, V	
ART UNIT	**PAPER NUMBER**
1645	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)
*U.S. GPO: 2000-472-000/45000

1- File Copy

Offic Action Summary	Applicati n No. 09/701,289	Applicant(s) LAMBERT ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

– The MAILING DATE f this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 3 October 2001 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) 1-7 and 16-34 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 8-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Applicant's response to the Restriction requirement filed in Paper No. 7 filed on October 3, 2001 is acknowledged. Applicant's election with traverse of Group II, claims 8-15 is acknowledged. Groups I and II-IX are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being to a non-elected invention.

The traversal is on the grounds that Groups II and III should be examined together because they share a common general inventive concept and should be considered together. These arguments have been fully considered but are not found to be persuasive for the reasons below:

The MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example as product and method of use, etc., but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.01). In the instant situation, the inventions of Groups II and III are drawn to distinct inventions which are a product and a method as described in the previous Office Action.

The literature search, particularly relevant in this art, is not co-extensive, because for example, Group II drawn to a method and Group III drawn to a method. Clearly different searches and issues are involved in the examination of each Group.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claim Objections

2. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 12 does not further limit claim 8.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8-15 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of "Gram +ve". "Gram +ve" should be changed to "Gram-positive". Correction is required.

4. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Claim 8 refers to figure 2, however, there is no figure submitted with the application. (see attached Bib sheet) Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 8-13 and 15 are rejected under 35 U.S. 102(b) as anticipated by Carruthers et al (*Journal of Clinical Microbiology, April 1984, p.552-554).*

Claims 8-13 and 15 are drawn to a method of testing for a gram-positive bacterial infection in a mammalian (typically human) subject, the method comprising the steps of: obtaining a sample of body fluid from the subject, contacting the sample with a composition comprising a compound having the structure shown in Figure 2, wherein n is an integer between 3 and 10 (inclusive) and X is H, OH, alkyl, aryl, amyl or an amino acid residue (optionally substituted) or a sugar reside (optionally substituted) and R and R^1 are hydrophobic or fatty acid chains (R may be the same as R^1 or different) and detecting binding of antibodies (if any) in the sample to the composition.

Carruthers et al teach a method of detecting antibody to staphylococcal Lipoteichoic acid (LTA) in a microenzyme-linked immunosorbent assay. Carruthers et al teach detection of antibody to cell components and extracellular products of *Staphylococcus aureus* solely or in combination may be useful in the serological diagnosis of serious *S. aureus* infections. Carruthers et al teach a purified staphylococcal LTA in a microenzyme-linked immunosorbent assay to examine human sera for antibody to the antigen (page 552, 1st column). Carruthers et al teach that sera used in the microenzyme-linked immunosorbent assay was obtained from patients with

prosthetic joint infections, patients with soft tissue infections, patients that had intravenous catheter-associated bacterial infections and one patient with an infected shunt (page 552, 2nd column). Carruthers, et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e.,that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Claims 8-13 and 15 are rejected under 35 U.S. 102(b) as anticipated by Wergeland et al (*Journal of Clinical Microbiology, June 1989, p. 1286-1291).*

Claims 8-13 and 15 are drawn to a method of testing for a gram-positive bacterial infection in a mammalian (typically human) subject, the method comprising the steps of: obtaining a sample of body fluid from the subject, contacting the sample with a composition comprising a compound having the structure shown in Figures 2, wherein n is an integer between 3 and 10 (inclusive) and X is H, OH, alkyl, aryl, amyl or an amino acid residue (optionally substituted) or a sugar reside (optionally substituted) and R and R^1 are hydrophobic or fatty acid chains (R may be the same as R^1 or different) and detecting binding of antibodies (if any) in the sample to the composition.

Wergeland et al teach a method of analyzing sera obtained from 66 blood donors wherein the sample is contacted with a Staphylococcal antigen composition comprising

Lipoteichoic acid, LTA (the compound of Figure 1), peptidoglycan, β-ribitol teichoic acid and peptidoglycan epitopes L-lys-D-Ala-D-Ala, L-lys-D-Ala and pentaglycine using an enzyme-linked immunosorbent assay (ELISA). Wergeland et al teach the antibodies react with staphylococcal antigens. Wergeland et al also teach the range of antibody values in the sera from the blood donors and patients with various staphylococcal infections are shown in Table 1 (page 1287). Wergeland et al teach that the total immunogloblin G (IgG), IgA and IgM were routinely determined by the immunological laboratory procedures for all blood donor and patient sera with a Nephelometer-Analyzer. Wergeland et al teach that the normal ranges of the immunoglobulin concentrations in adult sera were the ranges 7 to 18, 0.5 to 3.3 and 0.3 to 2.5 g/liter for IgG, IgA and IgM, respectively. Wergeland et al teach the use of a 5 μg/ml concentrated LTA in the ELISA assay. It would be inherent the LTA used in the ELISA of Wergeland et al is in substantially pure form. Wergeland, et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e.,that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wergeland et al in view of Raad *(The Lancet, London, March 21, 1998).*

Claims 8 and 14 are drawn to the method of claim 8 for diagnosing the presence of a Gram-positive infection associated with a central venous catheter, a cerebrospinal fluid shut or a prosthetic device.

Wergeland et al teach a method of analyzing sera obtained from 66 blood donors wherein the sample is contacted with a Staphylococcal antigen composition comprising Lipoteichoic acid, LTA (the compound of Figure 1), peptidoglycan, β-ribitol teichoic acid and peptidoglycan epitopes L-lys-D-Ala-D-Ala, L-lys-D-Ala and pentaglycine using an enzyme-linked immunosorbent assay (ELISA). Wergeland et al teach the antibodies reactive with the staphylococcal antigens. Wergeland et al also teach the range of antibody values in the sera from the blood donors and patients with various staphylococcal antigens are shown in Table 1 (page 1287). Wergeland et al teach that the total immunogloblin G (IgG), IgA and IgM were routinely determined by the immunological laboratory for all blood donors and patient sera with a Nephelometer-Analyzer. Wergeland et al teach that the normal ranges of the immunoglobulin

concentrations in adult sera were the ranges 7 to 18, 0.5 to 3.3 and 0.3 to 2.5 g/liter for IgG, IgA and IgM, respectively. Wergeland et al teach the use of a 5 μg/ml concentrated LTA in the ELISA assay. It would be inherent the LTA used in the ELISA of Wergeland et al is a substantially pure form.

Wergeland et al do not disclose patients with gram-positive infections associated with a central venous catheter, a cerebrospinal fluid shut or a prosthetic device.

Raad teaches that more than 150 million intravascular catheters are purchased annually by clinics and hospitals in the United States this includes more than five million central venous and pulmonary artery catheters. Raad further teaches that the reported frequency of bloodstream infections associated with various types of intravascular catheters have been estimated at about 400,000 episodes per year in the United States (page 1). Raad teaches that the organisms that cause vascular catheter related bloodstream infections (CRBSI) are *Streptococcus epidermidis, Staphylococcus aureus, Bacillus species* and *Corynebacterium species*. Raad teaches that other organisms that contaminate the hands of medical personnel are *Pseudomonas aeruginosa, Acinetobacter species, Stenotrophomonas maltophilia, Candida albicans* and *Candida parapsilosis*. Raad teaches that other organisms that are emerging as pathogens are *Micrococcus species, Achromobacter, Mycobacterium foruitum and M. chelonei*. Raad teaches that fungal organism such as *Malassezia furfur, Rhodotorula species, Fasarium species, Trichosporon species* and *Hansenula anomala* also have caused catheter infections (page 2).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to test gram-negative infections associated with intravascular catheters as taught by Raad using the method of testing gram-positive bacterial infections in sera as taught by Wergeland et al because Raad teaches that successful management of CRBSI, all depends upon early diagnosis, cost-effective prevention, effective treatment and the understanding of the pathogenesis of the gram-positive infection.

Pertinent Prior Art

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure *(Elliott, Journal of Antimicrobial Chemotherapy,43, 1999, p. 441-446, published November 13, 1997 and Olvoort, Journal of the Royal Netherlands Chemical Society, 10113, March 1982).*

Status of Claims

9. No claims are allowed.

Conclusion

10. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
October 23, 2001

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